



## Clinical evidence supporting the safety, stability and predictable visual performance of the 1stQ AddOn® Sulcus IOL family

- Visual quality after cataract surgery is coming into the spotlight and several new technologies are being developed to meet the ever-increasing demands of cataract surgeons and their patients
- Although laser vision correction has been described as an effective approach, due to the raising concerns about dry eye syndrome and other issues related to optical surface quality, many surgeons are looking for lens-based correctional options. A major concern of surgeons so far however has been the lack of scientific evidence on this very topic.
- We are very pleased to share with you that the safety, stability and the predictable visual performance of our **1stQ AddOn®** supplementary intraocular lenses have been confirmed by several clinical investigations released during the past few years.

# Safe in the Sulcus

## ■ Stable intraocular pressure.

No statistically significant difference in the IOP before and after the secondary IOL implantation could be measured. All eyes had an IOP in the physiological range ( $\leq 20$  mmHg) both during the surgery and throughout the postoperative follow-up period.<sup>1-3,6,7</sup>

## ■ Preserved endothelial integrity and function.

The convex-concave geometry of the 1stQ AddOn® IOLs help in maintaining endothelial structure and function. Only a negligible loss of  $2.00 \pm 1.58\%$  (range: 0.23 to 5.14%) of endothelial cells could be observed, which is much less, than the average loss during a routine cataract surgery with phacoemulsification.<sup>1</sup>

## ■ Sufficient interlenticular space to avoid interlenticular opacification.

The specific convex/concave optic design of the AddOn® lenses leaves an approximately 500  $\mu\text{m}$  space between the AddOn® and the capsular bag IOL, thus avoids any IOL touch and interlenticular opacification.<sup>1,7</sup>

## ■ No complications related to the secondary IOL implantation.

The IOL design is well suited for sulcus implantation. Unlike other platforms, the 1stQ AddOn® has not been associated with the well described problems of Sulcus IOL placement, like dislocation, iris capture, iris chafing, pigment dispersion syndrome, pupillary rupture or angle closure (secondary glaucoma), or any change in the IOL material.<sup>1-8</sup>

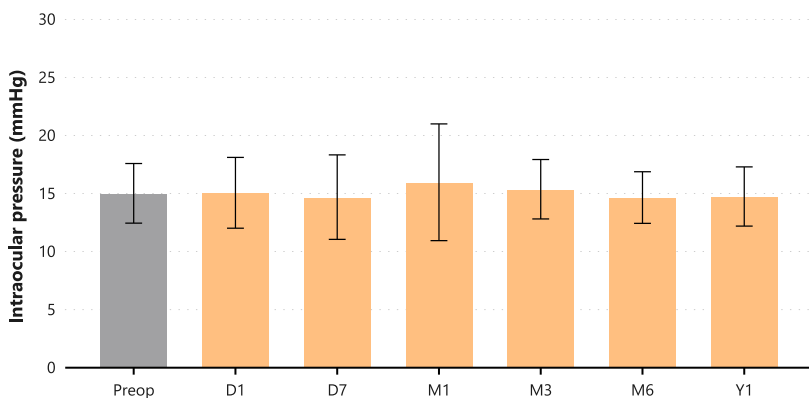


Figure 1. Intraocular pressure remains in the physiological range both during and after surgery (Srinivasan, 2019)

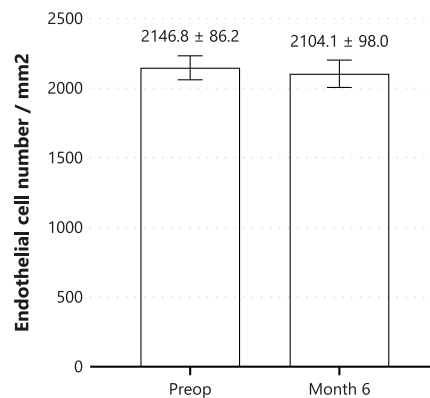


Figure 2. Endothelial cell loss during surgery is negligible. (Palomino-Bautista, 2020)

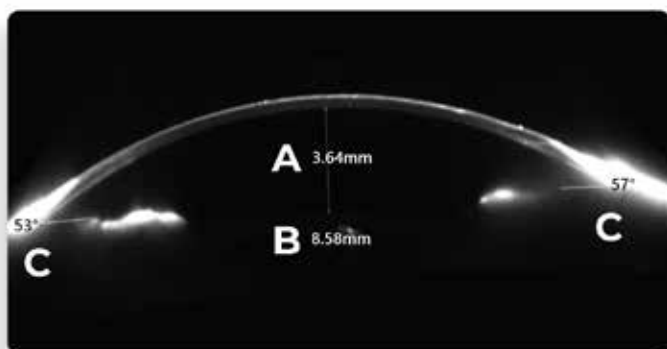


Figure 3. Postoperative anterior OCT image of the left eye.

- (A) The deep anterior chamber (3.64 mm) maintains endothelial integrity and function
- (B) An interlenticular space of 0.600 mm is wide enough to minimize the risk of interlenticular opacification.
- (C) Cornea angles are wide enough (53° and 57°) to maintain physiological function of the anterior segment and to prevent secondary glaucoma.

Courtesy by Prof. G. Scharioth (2018; Recklinghausen, Germany)

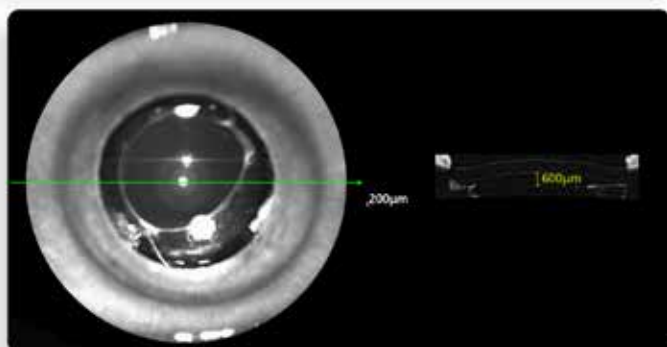


Figure 3. Anterior OCT image shows interlenticular space of 0.600 mm. Courtesy by Prof. G. Scharioth (Recklinghausen, Germany)

# Effective refractive correction

## ■ Predictable refractive outcomes.

The majority of eyes (87%<sup>1</sup>) achieve a refractive outcome (spherical equivalent, cylinder) within 0.5 D from the refractive target, while all eyes are usually within 1.0 D.<sup>1-5</sup> Residual refractive spherical equivalent is usually close to emmetropia (SEQ=  $-0.015 \pm 0.09$  D ; mean  $\pm$  SD).<sup>1</sup>

## ■ Excellent vision, without the need for further correction.

Uncorrected distance vision is usually within 1 line from the best corrected distance vision (100%). 87% or a higher percentage of eyes achieve an UDVA of 6/7.5 (20/25; 0.1 logMAR) or better.<sup>4</sup> The mean UDVA is usually better, than 0.05 logMAR), and does not require further correction.<sup>1-5</sup>

## ■ Presbyopia-correction and spectacle independence.

All eyes (100%) are able to achieve spectacle independence for all distances. Defocus curve of the 1stQ AddOn® Trifocal lens is identical to that of a Belgian trifocal primary IOL, regarded as the first trifocal lens.<sup>1</sup>

## ■ Efficient astigmatism-correction.

The majority of eyes (89%) had residual refractive astigmatism of  $\leq 0.50$  D, and no eye had more than 0.75 D after secondary IOL implantation (100%).<sup>3</sup> Irregular astigmatism after PKP was also found to be successfully compensated with the 1stQ AddOn® IOL family.<sup>6</sup>

## ■ Excellent quality of vision- low levels of dysphotopsia.

Dysphotopic events are rare, but if present, the visual comfort of patients remains still unaffected. Patients report good quality vision even in low light conditions.<sup>5</sup>

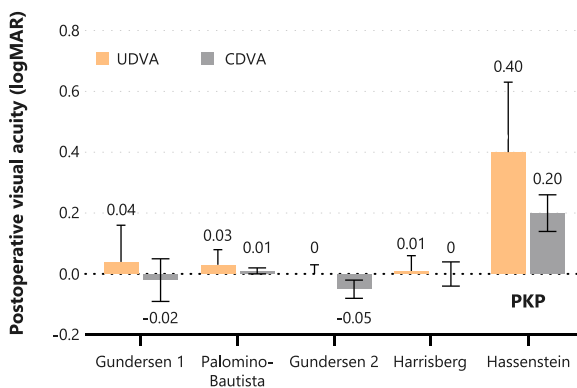


Figure 5. Uncorrected and corrected distance visual acuities reported by multiple clinical studies following the implantation of the 1stQ AddOn® IOL.

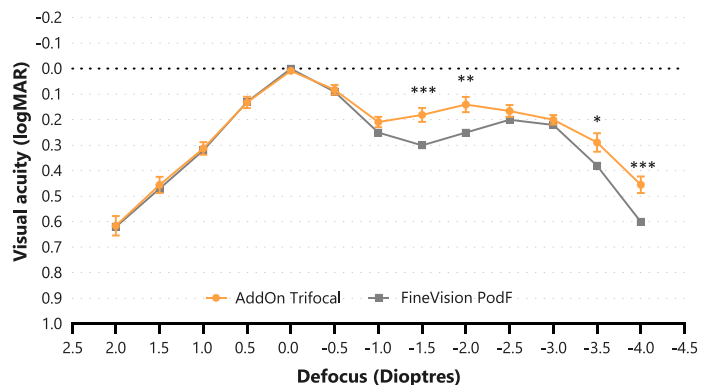


Figure 6. Monocular defocus curve of the 1stQ AddOn® IOL shows superior visual acuity in intermediate and near ranges compared to the trifocal capsular bag intraocular lens. (Palomino-Bautista, 2020)

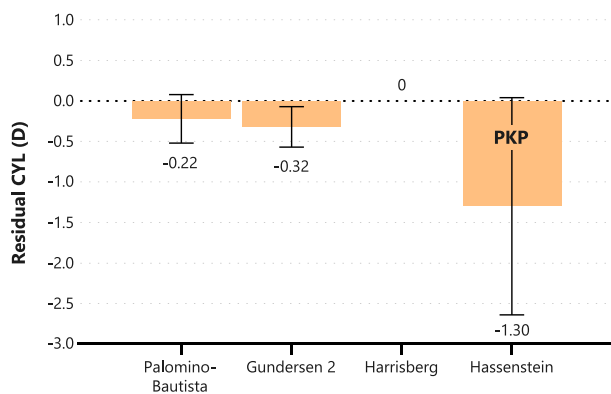
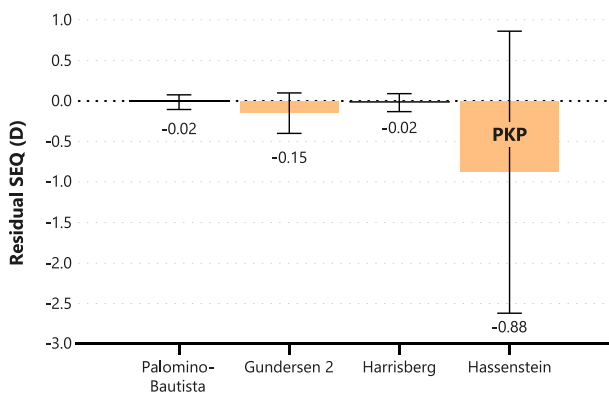


Figure 7. Residual spherical equivalent refraction (A) and residual astigmatism (B) are close to the target refraction (multiple studies). Bars represent mean  $\pm$  standard deviation in each case. The last dataset (Hassenstein) represents data from post-keratoplasty eyes.

# Stability on the long-term

## ■ Successful implantation in a wide range of axial lengths.

Both cadaver and clinical studies confirm that the 1stQ AddOn® IOLs can maintain stable position in eyes with a wide variety of axial lengths.<sup>2,8</sup> Moreover, the AddOn® IOLs work properly with any type (monofocal, multifocal, EDoF) and power of primary lenses.<sup>2</sup>

## ■ Easy and accurate positioning.

No 1stQ Toric IOLs (0%) needed repositioning. Competitor models are reported to requiring repositioning up to 62 %.<sup>3</sup> However, intact zonular complex is a crucial prerequisite for long-term stability.<sup>2</sup>

## ■ High rotational stability during the whole investigated period.

The mean change in orientation, compared to the surgical IOL-position was near zero ( $-0.1^\circ \pm 6.3^\circ$ ), with a mean absolute change of  $4.9^\circ \pm 3.7^\circ$ . This confirms a remarkably higher stability than that reported on another, widely used astigmatism-correcting sulcus lens ( $17^\circ$ ).<sup>3</sup>

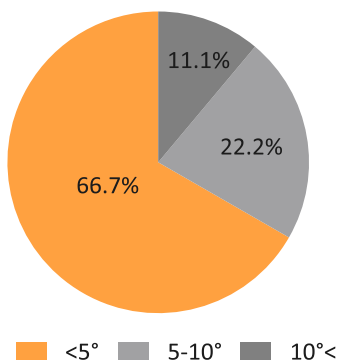


Figure 8. Majority of the 1stQ AddOn® Toric IOLs maintain surgical position postoperatively. Off-axis rotation is minimal. (Gundersen, 2020)

	1stQ AddOn® Toric	Sulcoflex Toric 653T
Reported by	Gundersen 2020	McLintock, 2019
Eyes	18	51
Follow-up (months)	1 month - 4.5 years	at least 3 months
Mean rotation (°)	$4.9 \pm 3.7^\circ$	$6.17^\circ$
Repositioning (% of eyes)	0%	62%
Average times of repositioning	0	2.3 times

Figure 9. Comparison of the rotational stability of two toric supplementary IOL models. The 1stQ AddOn® IOL seems to be more stable in the long-term. (Gundersen, 2020; McIntock, 2019)

## Conclusion

The 1stQ AddOn® intraocular lenses offer a safe and efficient option for pseudophakic patients to effectively reduce their residual refractive errors or enable spectacle independence; and thereby increase visual quality after cataract surgery.

**Further reading** **1. Palomino-Bautista C**, Sánchez-Jean R, Carmona Gonzales D, Romero Domínguez M, Castillo Gómez A. Spectacle independence for pseudophakic patients – Experience with a trifocal supplementary add-on intraocular lens. *Clin Ophthalmol.* 2020; 14:1043–1054. **2. Gundersen KG**, Potvin R. A review of results after implantation of a secondary intraocular lens to correct residual refractive error after cataract surgery. *Clin Ophthalmol.* 2017 Oct 3; 11: 1791-1796. doi: 10.2147/OPTH.S144675. eCollection 2017. **3. Gundersen KG**, Potvin R. Refractive and visual outcomes after implantation of a secondary toric sulcus intraocular lenses. *Clin Ophthalmol.* 2020; 14:1337-1342. **4. McIntock C**, McKelvie J, Apel A. Outcomes of 1stQ toric supplementary intraocular lenses for residual astigmatic refractive error in pseudophakic eyes. Presented at the RANZCO Congress in 2019, Sydney, Australia. *Clin Exp Ophthalmol.* 2019; 47:Suppl. 1:46. **5. Harrisberg B**. Comparison of refractive and visual outcomes in cataract patients implanted with either premium primary IOLs or with dual implantation approach. Presented in the RANZCO NSW Congress in 2020, Newcastle, NSW, Australia. **6. Hassenstein A**, Niemeck F, Giannakakis K, Klemm M. [Toric add-on intraocular lenses for correction of high astigmatism after pseudophakic keratoplasty]. [Article in German]. *Ophthalmologe.* 2017 Jun;114(6):549-555. **7. Srinivasan S**. Implantation of Scharioth macula lens in patients with age-related macular degeneration: results of a prospective European multicentre clinical trial. *BMJ Open Ophthalmol.* 2019 Jul 7;4(1):e000322. doi: 10.1136/bmjophth-2019-000322. eCollection 2019. **8. Reiter N**, Werner L, Guan J, Li J, Tsaousis KT, Mamalis N, Srinivasan S. Assessment of a new hydrophilic acrylic supplementary IOL for sulcus fixation in pseudophakic cadaver eyes. *Eye (Lond).* 2017 May;31(5):802-809. doi: 10.1038/eye.2016.310. Epub 2017 Jan 20. **9. McIntock CA**, McKelvie J, Gatziofias Z, Wilson JJ, Stephensen DC, Apel AJG. Outcomes of toric supplementary intraocular lenses for residual astigmatic refractive error in pseudophakic eyes. *Int Ophthalmol.* 2019;39(9):1965-1972.